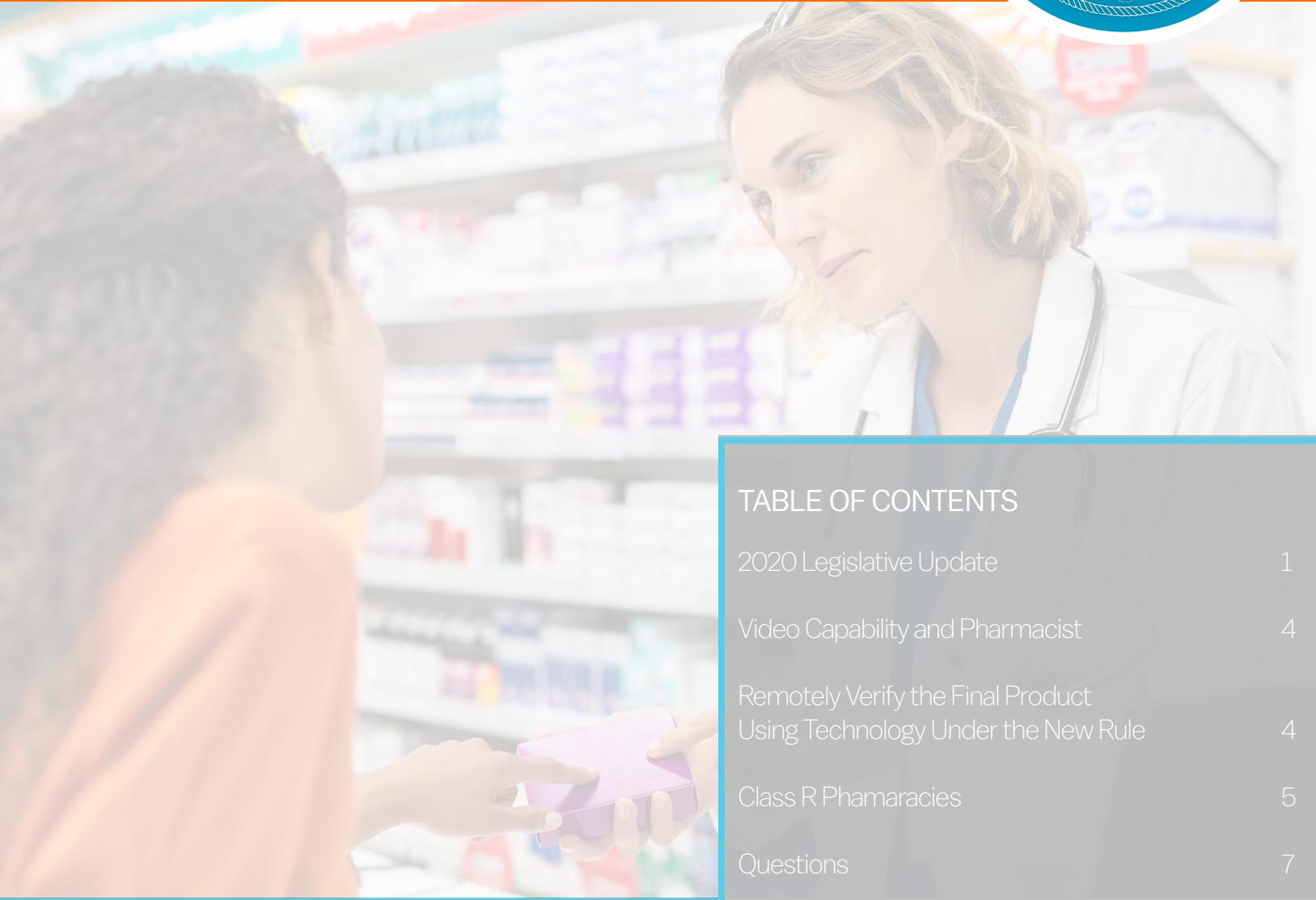


NEWSLETTER

AUGUST 2020



2020 LEGISLATIVE AND RULE UPDATE

The 2020 legislative session has closed! Several pieces of pharmacy legislation were enacted this year that will impact pharmacy practice. The Board has also promulgated multiple new pharmacy rules. A summary of the new provisions is provided below.

The following summary is not a comprehensive review of all new legislation/rules. Licensees should independently review statutory/rule changes to ensure compliance. A link to new legislation/rules is available on the Board's website at: <https://pr.mo.gov/pharmacists-rules-statutes.asp>

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NEW LEGISLATION (Effective August 28, 2020)

The following new statutory provisions will be effective on August 28, 2020:

- [§ 338.220](#): Establishes a **Class Q Charitable Pharmacy** permit classification. The Board is drafting rules to define a Class Q pharmacy and establish Class Q operational standards. Class Q pharmacy permits will be available once the Board's rules are finalized. Interested parties should monitor the Board's website for additional information.
- [§ 338.220/§ 338.215](#): Establishes a Class R Remote Dispensing Site Pharmacy. Class R pharmacies may be staffed by a qualified pharmacy technician or intern pharmacist who is remotely supervised by a Missouri licensed pharmacist located at a supervising pharmacy. Prescriptions may be prepared and dispensed from a Class R pharmacy when a pharmacist is not present, as provided by statute and the Board's rules. Class R pharmacies must be at least ten (10) miles away from a "retail" pharmacy, unless otherwise approved by the Board.

The Board anticipates filing rules in the fall of 2020 to implement Class R licensure (followed by the statutory rulemaking process). Class R permits will be available once the rules are finalized. Interested parties should monitor the Board's website for additional developments.

NEW RULES (Effective August 30, 2020)

The Board continues to focus on streamlining and modernizing Missouri's pharmacy rules. The Board's goal is to adopt flexible standards of practice that will protect patients and ensure safe delivery of pharmacy services. A key element of the Board's focus is the role of pharmacy technicians and intern pharmacists assisting in the practice of pharmacy. In line with the Board's initiative, the following new/amended rules will be effective on **August 30, 2020**:

20 CSR 2220-2.710 (PHARMACY TECHNICIAN AND INTERN PHARMACIST SUPERVISION)

Section 338.010.1, RSMo, provides a pharmacy technician/intern pharmacist may assist a pharmacist in the practice of pharmacy under the "direct supervision" of a pharmacist. Previously "direct supervision" was not defined by Missouri law. Newly promulgated rule 20 CSR 2220-2.710 would define direct supervision and allow licensees to supervise pharmacy technicians/intern pharmacists via technology, subject to rule requirements.

20 CSR 2220-2.710 defines "direct supervision" as supervision by a Missouri licensed pharmacist who: (1) is "readily and immediately available" at all times delegated tasks are being performed, and (2) provides personal assistance, direction, and approval when delegated tasks are being performed. [20 CSR 2220-2.710(1)]

"Readily and immediately available" means the supervising pharmacist must be on the same physical premises as the pharmacy technician/ intern pharmacist, or if not on the same physical premises, technology can be used to supervise the technician's/intern pharmacist's activities [20 CSR 2220-2.710(1)]. The required technology must allow the pharmacist to communicate with and monitor pharmacy technician(s)/intern pharmacist(s) in a manner that is sufficient to provide the personal assistance, direction, and approval needed to verify and ensure delegated tasks are safely and properly performed.



Technology **cannot** be used to supervise technicians/intern pharmacists who are compounding, preparing, dispensing or dispensing medication/prescriptions, except as allowed for Class R pharmacies. 20 CSR 2220-2.010(1)(A) and (B) still provide a licensed pharmacist must be physically present within the confines of the dispensing area and able to render immediate assistance whenever medication is compounded, prepared, dispensed or provided to/for patients. While the Board will be reviewing this requirement in the future, 20 CSR 2220-2.010 is still effective and mandatory.

The following additional requirements apply if supervision is performed via technology, as authorized by 20 CSR 2220-2.710:

1. The pharmacy technician/intern pharmacist must have completed employer approved training in the activities performed and must have an initial and, if applicable, an annual documented assessment of competency. The length and content of the required training is in the pharmacy's discretion. Documentation of the completed training and competency assessment must be maintained in the pharmacy's records for at least two (2) years; and
2. The supervising pharmacist and the permit holder must maintain an audit trail of prescription/medication order data entry and any modifications to a patient record performed by a pharmacy technician/intern pharmacist being supervised via technology. The required documentation must include the identity of the pharmacy technician/intern pharmacist performing data entry or modifying patient records (e.g., initials, user code). Documentation must be maintained in the pharmacy's records for a minimum of five (5) years; and
3. The supervising pharmacist and the permit holder must ensure all applicable state and federal laws are fully observed.

Examples of Supervision Allowed by 20 CSR 2220-2.710:

- The supervising pharmacist is on a lunch break on the pharmacy's premises but is available to answer pharmacy technician/intern pharmacist questions and provide needed direction/assistance for delegated tasks.**
- A pharmacist is not present at the pharmacy, however, a Missouri licensed pharmacist at another Missouri licensed pharmacy is supervising pharmacy technician/intern pharmacist activities using technology that complies with 20 CSR 2220-2.710.**
- A pharmacist is running late to open the pharmacy but is able to communicate with pharmacy technicians/intern pharmacists and monitor delegated tasks using technology that complies with 20 CSR 2220-2.710.

**Pharmacy technicians/intern pharmacists cannot prepare, compound, dispense or provide medication unless a pharmacist is physically present in the dispensing area and supervising.

Examples of Supervision **Not** Allowed By 20 CSR 2220-2.710:

- A pharmacist is at lunch and has asked not to be interrupted and is not available to answer questions from pharmacy staff. The pharmacist is not reasonably available under 20 CSR 2220-2.710 and pharmacy technician/intern pharmacist activities must terminate until the pharmacist is able to directly supervise in compliance with the rule (the no pharmacist on duty sign must also be posted).



- A pharmacist is on break in the pharmacy's parking lot and is not available for questions or to assist pharmacy technicians/intern pharmacists. The pharmacist is not reasonably available under 20 CSR 2220-2.710 and pharmacy technician/intern pharmacist activities must terminate until the pharmacy becomes readily available (the no pharmacist on duty sign must also be posted).
- A pharmacist is remotely supervising the pharmacy using technology. The pharmacist can communicate with pharmacy staff but cannot monitor what activities staff are performing. A pharmacist is not reasonably available under 20 CSR 2220-2.710. Supervision technology must allow the pharmacist to both communicate with and monitor pharmacy staff.

The staff pharmacist is running late and the pharmacist-in-charge has authorized pharmacy staff to dispense prescriptions in the will-call bin that were previously verified by a pharmacist. No pharmacist is on the premises, however, technicians are being supervised by a Missouri licensed pharmacist using technology that complies with 20 CSR 2220-2.710. Remote supervision of this activity is not allowed. Pharmacy technicians/intern pharmacists cannot compound, prepare, dispense or provide medication unless a pharmacist is physically present in the dispensing area.

IS VIDEO CAPABILITY REQUIRED IF A PHARMACIST IS SUPERVISING VIA TECHNOLOGY?

20 CSR 2220-2.710(2)(A) provides the required technology must allow the supervising pharmacist to communicate with and monitor the pharmacy technician's/intern pharmacist's activities while delegated tasks are being performed. The Board recommends two-way video and audio capability as a best practice. However, pharmacists and permit holders should use their discretion to determine the technology needed to adequately communicate with staff and monitor delegated activities. Both the supervising pharmacist and permit holder are responsible for compliance and ensuring pharmacy activities are properly and safely performed. *Note: Technology is only required to supervise technicians/intern pharmacists if a pharmacist is not physically present on the pharmacy's premises and actively supervising.*

CAN A PHARMACIST REMOTELY VERIFY THE FINAL PRODUCT USING TECHNOLOGY UNDER THE NEW RULE?

No. 20 CSR 2220-2.010(1)(B) provides a pharmacist must personally inspect and verify the accuracy of a prescription's contents and the affixed label prior to dispensing. 20 CSR 2220-2.710 does not amend this requirement and does not allow pharmacists to remotely verify prescriptions via technology (see below for Class R pharmacies).

COVID-19 Waiver: The Board issued a COVID-19 waiver to allow pharmacists to remotely verify the final prescription product via technology during the COVID-19 State of Emergency, if needed to provide disaster or emergency relief and a pharmacist cannot promptly perform the required physical verification (see the Board's website for full waiver requirements). The COVID-19 waiver is effective until December 30, 2020. Licensees may continue to remotely verify medication under the waiver through December 30, 2020.



WHAT ABOUT CLASS R PHARMACIES?

Newly enacted § 338.215 would allow pharmacists to remotely supervise pharmacy technicians/intern pharmacists compounding, preparing or dispensing prescriptions at a Class R Remote Dispensing Site pharmacy, including, remote final product verification.

The Board is in the process of drafting required rules to implement § 338.215 and anticipates filing proposed rules for public comment in the fall of 2020. Class R permits will be available after the Board's rules are officially promulgated. Interested parties should monitor the Board's website.

20 CSR 2220-2.725 (REMOTE DATA ENTRY)

20 CSR 2220-2.725 allows pharmacy technicians and intern pharmacists to perform data entry activities at a remote data entry site (e.g., from home).

1. Remote data entry sites must be located in Missouri (see below for current COVID-19 waiver) and must be supervised by a Missouri licensed pharmacy located in Missouri. The supervising pharmacy must maintain a current list of all remote data entry sites being used and maintain policies and procedures governing all aspects of remote data entry site operations. The policy and procedure manual must be annually reviewed by the pharmacist-in-charge (see 20 CSR 2220-2.725(4) for *additional minimum policy and procedure requirements*).
2. Adequate security and supervision must be maintained at all times to prevent unauthorized access to the remote data entry site and equipment. Confidential records must be securely maintained. Any security breach of remote data entry equipment or confidential records must be documented and reported to the board in writing within seven (7) days of the breach.
3. Paper patient or prescription records may not be generated, located, or maintained at a remote data entry site.
4. Pharmacy technicians/intern pharmacists operating at a remote data entry site must be competent in the duties performed. Pharmacy technicians/intern pharmacists must have completed employer approved training in the activities performed and must have an initial and, if applicable, annual assessment of competency. The length and content of the required training is in the pharmacy's discretion. Documentation of training and competency assessment(s) must be maintained in the pharmacy's records for at least two (2) years.
5. A pharmacist must be available to respond to technician/intern pharmacist questions at all times a remote data entry site is in operation. A sufficient mechanism must be in place to allow the supervising pharmacist and pharmacy technician/intern pharmacist to communicate in real-time when needed. Data entry may not be performed at a remote data entry site if the required real-time communication mechanism is not operating or available. The supervising pharmacist must provide the personal assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed.
6. Except as otherwise provided by state and federal requirements, the remote data entry site and the



supervising pharmacy must share a common database or prescription record-keeping system that allows real-time, online access to relevant patient profile information by both the supervising pharmacy and the remote site.

7. The identity of the pharmacy technician or intern pharmacist responsible for remotely entering, validating, or modifying data at a remote data entry site must be electronically documented/recorded in the pharmacy's records and maintained for a minimum of five (5) years (e.g., initials/computer code).

20 CSR 2220-2.725 is similar to the COVID-19 waiver previously issued by the Board with a key exception:

- Unlike the COVID-19 waiver, 20 CSR 2220-2.725 provides a remote data entry site must be located in Missouri. Pharmacy technicians/intern pharmacists cannot perform remote data entry activities under 20 CSR 2220-2.725 from a residence or non-pharmacy facility that is located in another state. For example, pharmacy technicians cannot perform remote data entry activities under the rule from their home in Illinois. The COVID-19 remote data entry waiver is effective through **December 30, 2020**. Absent a waiver extension, remote data entry sites must be physically located in Missouri, beginning December 31, 2020.
- 20 CSR 2220-2.725 only applies to remote data entry activities performed by a pharmacy technician/intern pharmacist. A Missouri licensed pharmacist may continue to perform non-dispensing activities including data entry from either a Missouri or non-Missouri location, as authorized by 20 CSR 2220-6.055.

20 CSR 2220-6.055 (NON-DISPENSING ACTIVITIES)

20 CSR 2220-6.055 has been amended to allow pharmacy technicians and intern pharmacists to assist with non-dispensing activities outside of a pharmacy, if:

1. The pharmacy technician/intern pharmacist is under the direct supervision of a Missouri licensed pharmacist who is "readily and immediately available," as required by 20 CSR 2220-2.710. The pharmacist must be physically present at the offsite location, or the technician/intern pharmacist must be supervised by a Missouri licensed pharmacist using technology that complies with 20 CSR 2220-2.710 (see 20 CSR 2220-2.710 summary above); and
2. A pharmacist must be available to respond to pharmacy technician/intern pharmacist questions at all times the technician/intern pharmacist is assisting with non-dispensing activities outside of a pharmacy. A sufficient HIPAA compliant mechanism must be in place to allow real-time communication between the pharmacist and pharmacy technician/intern pharmacist when needed (e.g., phone, audio/video technology); and
3. The pharmacy technician/intern pharmacist assisting must have completed employer approved training in the activities performed off-site. Training length and content are in the pharmacy's discretion. An initial proficiency assessment for the technician/intern pharmacist must be completed and, if applicable, an annual proficiency assessment thereafter. Documentation of the completed training and proficiency assessment must be maintained in the pharmacy's records; and



4. Adequate security and supervision must be maintained to ensure confidentiality of patient information/records; and
5. Similar to current law, pharmacy technicians cannot perform any activity that requires the professional judgment of a pharmacist.

Although 20 CSR 2220-6.055 allows offsite activities, pharmacy technicians/intern pharmacists cannot receive or accept a verbal or written prescription outside of a Missouri licensed pharmacy. *This restriction is mandated by § 338.095.5 and cannot be waived by the Board.*

Note: 20 CSR 2220-6.055 does not apply to delivery drivers delivering filled prescriptions/medication orders who are not performing pharmacy technician activities.

QUESTIONS?

Questions regarding the new rules/legislation may be submitted to the Board office at compliance@pr.mo.gov or (573) 751-0091. Alternatively, licensees may contact their Inspector (see [Inspector contact list](#)).



Rule/Statutory Comparison

	Technician/Intern Supervision (20 CSR 2220-2.710) <i>*Tech is on-site & RPh is off-site/not available</i>	Remote Data Entry Site (20 CSR 2220-7.025)	Off-Site Non-Dispensing Activities (20 CSR 2220-6.055)	Class R Remote Dispensing Pharmacy Sites (§ 338.215)
Technology assisted supervision?	✓	✓	✓	✓
Real-time audio communication mechanism between pharmacist & technician/intern pharmacist?	"Sufficient" communication method required; Real-time communication method recommended but not required	✓	✓	✓
Video technology?	* If needed to verify and ensure activities are safely and properly performed.	* If needed to verify and ensure activities are safely and properly performed.	* If needed to verify and ensure activities are safely and properly performed.	✓
Completion of employer training?	✓	✓	✓	* To be determined
Initial & annual competency assessment?	✓	✓	✓	* To be determined



Remote Supervision Authorized Activities

**Pharmacist is not physically present on-site
& technology is used to directly supervise technician/intern**

	Technician/Intern Supervision (20 CSR 2220-2.710) <i>*Tech is on-site & RPh is off-site/not available</i>	Remote Data Entry Site (20 CSR 2220-7.025)	Off-Site Non-Dispensing Activities (20 CSR 2220-6.055)	Class R Remote Dispensing Pharmacy Sites (§ 338.215)
Compounding?	✗	✗	✗	✓
Counting, filling or preparing medication/prescriptions?	✗	✗	✗	✓
Dispensing/providing final prescription to patient (even if verified by a pharmacist)?	✗	✗	✗	✓
Data entry (e.g., prescriptions, patient/medical records, insurance information, etc.)?	✓	✓	✓	✓
Accept written prescriptions (paper or faxed)?*	✓*	✗	✗	✓
Accept verbal prescriptions?*	✓*	✗	✗	✓

*Technician/ intern must be on the premises of a Missouri licensed pharmacy



BNDD'S 2020 Summer Newsletter

**Is Available Now On BNDD's
Website:**

See the following excerpt from BNDD's Summer 2020 Newsletter. NPLEx questions should be sent to BNDD at bnnd@health.mo.gov

PHARMACIES JOINING NPLEX PSEUDOEPHEDRINE TRACKING DATABASE

NPLEx stands for the National Precursor Log Exchange. This is the statewide database that tracks the sales of methamphetamine precursor products. There are currently approximately 1,369 retail pharmacies in Missouri. Available information at this time shows that 1,288 are available to use the NPLEx database. A review has shown that there are 49 local jurisdictions that have passed a local ordinance to require a mandatory prescription. This impacts approximately 81 pharmacies. Governor Parson signed HB1682 in July 2020 that changes the amounts of dispensing to only 7.2 grams per month and no more than 43.2 grams in a 12-month period. The new law also abolishes all local ordinances that require a prescription so that a prescription is not mandatory. This means the pharmacies in those locations will have to start using the NPLEx database. The new law goes into effect on August 28, 2020. To join the database, pharmacies may visit the website of Appriss, Inc. at <https://apprisshealth.com> or they may Google "NPLEx". There is a link on the page for contact information and the pharmacies can ask about joining the system. The existing contract provides for technical support, a toll free 800 number for calls and online tutorial videos to train staff.